REMARKS

In his Office Action of July 5, 2006, the Examiner has determined that of claims 1 – 110 that were pending in the case:

- Claims 1-7, 9-11, 15, 17, 19-34, 36-38, 42, 44, 46-69, 71-74, 78, 80, 82-97, 99-102, 106, 108, and 110 were rejected under 35 USC 102(b) as anticipated by Hanover et al. (US 5,196,002).
- Claims 12-14, 18, 39-41, 45, 75-77, 81, 103-105 and 109 were rejected under 35 USC 103(a) as obvious over Hanover et al, in view of Duhaylongsod et al (US 6,127,410).
- Claims 19, 46, 64 and 92 were rejected under 35 USC 103(a) as obvious over Hanover et al.
- Claims 8, 16, 35, 43, 70, 79, 98 and 107 would be allowable, if re-written in independent form.

Claim Rejections – 35 USC § 102(b) – Hanover et al.

Claims 1-7, 9-11, 15, 17, 19-34, 36-38, 42, 44, 46-69, 71-74, 78, 80, 82-97, 99-102, 106, 108, and 110 were rejected under 35 USC 102(b) as anticipated by Hanover et al. (US 5,196,002).

The Examiner's rejections are respectfully traversed.

Yet, in order to expedite prosecution, independent claims 1, 28, 55, and 83 have been amended, to better distinguish them over the cited art.

Thus, amended claim 1 recites:

"1. An oral device for controlled drug release, comprising:

a reservoir containing a drug;

an electronic drug release mechanism, for providing said controlled drug release; and

an oral anchoring element, for configuring the oral device for insertion to an oral cavity of a subject. "

The oral anchoring element is further defined, for example, in claims 22 and 23, as follows:

"22. The device of claim 1, wherein said oral anchoring element is a dental implement, selected from the group consisting of a prosthetic tooth crown, a dental bridge, a

dental three-unit bridge, dental implant, partial dentures, full dentures, braces, a molar band, a night guard, and a mouth guard."

"23. The device of claim 1, wherein said oral anchoring element is selected from the group consisting of an anchor, configured for securing to the oral mucosa, and an anchor configured for securing to a jawbone."

An important feature, associated with the dental implement, is its rendering an easily accessible removable component possible. The removable component may be reached, without removing the implanted device, and without surgery or another invasive procedure. The removable component may be used, for example, for refilling or replacing a drug reservoir or a power source, as illustrated in Figures 8C and 8D of the present application, and as recited, for example, in claim 27, as follows:

"27. The device of claim 22, wherein said device is adapted to be permanently inserted in the oral cavity of the subject, and said device further includes a removable component, which houses at least one of said drug reservoir and said power source, said removable component being accessible without an invasive procedure."

The accessibility of the removable component is a unique advantage of the dental implement for housing the device for controlled drug release; while the device itself may be permanently inserted, a portion thereof, for example, the tooth crown, remains easily accessible without an invasive procedure, and may include the removable component. In this way, the difficult issue of replacing components and replenishing the drug in an implanted drug delivery device is solved.

Independent claims 28, 55, and 83 similarly recite an oral anchoring element or a dental implement that serves as the oral anchoring element.

Respectfully, Hanover et al. teach an implantable drug delivery system, for implanting in a body of a person or an animal. Yet, they do not teach the specific implantation in an oral cavity. In fact, their only reference to oral administration is in their Column 1, Lines 17-18, as follows:

"(or administering orally)",

in reference to the ***prior art*** oral administration of drugs, by ***swallowing, drinking, or sucking***. That this is their meaning is made apparent by the continuation of the paragraph, Lines 19 – 22:

"...this may require finding and rounding up the animals, administering the desired drug (or different drugs), and then releasing the animals until the next drug administration is due."

Clearly, an automatic controlled drug delivery device will not require rounding up the animals for each administration. But in their background, Hanover et al. are not referring to an automatic controlled drug delivery device. Rather, they are relating to the old fashioned drug administration, by swallowing a pill or by drinking medicine in a liquid form.

Respectfully, Applicant maintains that the Examiner has erred in stating that Hanover et al. teach the use of dental implements and oral anchors in their Figures 6 and 7. In fact, their Figures 6 and 7 make no reference to anything dental. Element 348 of Figure 7, which the Examiner cites (see the bottom of page 5 of the Office Action) as an anchor that may be secured to the oral mucosa or to the jawbone, is in fact an oscillator 348 (see their Column 5, line 46). The following, from Hanover et al., Column 5, Lines 24 – 60, illustrates that there is no reference to the oral cavity or to an oral implement in connection with their Figures 6 or 7:

"FIGS. 6 and 7 show respectively a side, cross-sectional view of another embodiment of an implantable drug delivery system, and a top plan view of the release mechanism of the system. The FIGS. 6 and 7 system include a housing 304 having a base end 308 and a discharge end 312. A passive one-way valve 316 is disposed in the discharge end of the housing to allow release of drug formulation contained in the housing when a certain fluid pressure is applied from inside the housing to the valve.

...

Also disposed in the housing 304 is a coil spring 340 which extends from a bottom wall at the base end of the housing 308 upwardly into the hollow 324 of the plunger 320. A battery 344, ***oscillator 348*** and timing circuit 352 are disposed ..."

Additionally, the Examiner maintains that Hanover et al. teach a removable component which may include the drug reservoir (their element 336) and a power source (their element 344) both of Fig. 6. Yet while their drug reservoir 336 is indeed situated on their plunger 320, which has a sliding motion, the sliding motion is connected with drug release under normal operation, and not with replacement of components, as taught and claimed by the present invention. This is made clear from their Column 5, Line 61 - Column 6, Line 8, as follows:

"A plurality of different length tethers or fibers 360 are attached at one end to the underside of the plunger 320 and at the other end to release nodes 364 disposed on the circuit card 356. The tethers 360 serve to hold the plunger in place and prevent it from being moved upwardly toward the discharge end of the housing by the spring 340 until selected tethers are released from the circuit cards. In particular, each of the tethers, being a different length, serve to hold or retain the plunger 320 at different distances away from the circuit card 356 until the tether holding the plunger at a respective length is released from its corresponding release node 364. ***In this manner, the tethers 360 can be successively released to allow a stepwise movement upwardly of the plunger 320 to successively discharge boluses of drug formulation contained in the reservoir 336."***

Moreover, Hanover et al. do not teach that the plunger is easily accessible, after implantation, for replacing components without surgery or another invasive procedure.

Respectfully, Applicant maintains that the Examiner has erred in a few other citations from Hanover et al., for example:

The Examiner maintains that Hanover et al. disclose at least one local sensor, in their Fig. 6 and Column 3, Lines 53 – 68, Column 4, Lines 1 - 9, and Column 5, Lines 43 – 60, yet no reference to a sensor was found there or anywhere in Hanover et al.

The Examiner maintains that Hanover et al. disclose at least two local sensors, ibid, yet no reference to any sensors was found.

The Examiner maintains that Hanover et al. disclose a physiological sensor, in their Fig. 7, element 364. Yet, elements 364 of Figure 7 are in fact, release nodes, as stated in Hanover et al. Column 5, lines 61 – 64:

"A plurality of different length tethers or fibers 360 are attached at one end to the underside of the plunger 320 and at the other end to ***release nodes 364*** disposed on the circuit card 356."

The Examiner maintains that Hanover et al. disclose a status sensor, in their Fig. 7, as element 364, and in their Figure 6, as element 352. Yet, again, elements 364 of Figure 7 are release nodes, as stated hereinabove. Element 352 is a timing circuit, as stated in Hanover et al. Column 6, Lines 9 – 20:

"The release nodes 364 are composed of a material (e.g., ultra-high-modulus polyethylene) capable of holding the ends of the respective tethers 360 until the material is activated or ignited (for example by a pyrotechnic material represented at 365) in response to an electrical signal to either sever or release the corresponding tether end. The pyrotechnic material 365 responds to electrical signals, referred to as "release signals," generated by the described electrical components. Each release node 364 is coupled to the ***timing circuit 352*** which selectively supplies an electrical release signal from the battery 344 to the nodes."

In contrast, to the teachings of Hanover et al., the present invention teaches the use of the oral cavity as the site for inserting a device for controlled drug delivery, the device being specifically configured for the oral cavity. This is taught by the present application and recited by claim 1 and the other independent claims, as shown and discussed hereinabove. The oral cavity is particularly advantageous, for the following reasons:

1. the oral cavity is easily accessible; the oral device may be inserted without a traumatic, even dangerous surgery, which may be associated with implantation in a blood vessel, in the stomach, or within a muscle.
2. moreover, while the dental implement may be permanently inserted, and fixed in place, a portion thereof, for example, the tooth crown, remains easily accessible without surgery or another invasive procedure, and may include a removable component, which houses at least one of a drug reservoir and a power source, thus enabling replenishing the drug or replacing components without surgery or another invasive procedure;
3. the oral cavity allows for buccal and(or) sublingual absorption of drugs released by the oral device; these absorption forms are ideal since they avoid both the gastrointestinal tract and its losses and the pre-systemic, first-pass metabolism, in the liver.

Respectfully, Applicant maintains that amended independent claims 1, 28, 55, and 83, and the claims that depend from them are novel and unobvious over Hanover et al. (US 5,196,002).

Claim Rejections – 35 USC § 103(a) – Hanover et al. in view of Duhaylongsod et al.

Claims 12-14, 18, 39-41, 45, 75-77, 81, 103-105 and 109 were rejected under 35 USC 103(a) as obvious over Hanover et al, in view of Duhaylongsod et al. (US 6,127,410).

Respectfully, each of claims 12-14, 18, 39-41, 45, 75-77, 81, 103-105 and 109 is dependent on one of amended independent claims 1, 28, 55, and 83. Applicant maintains that the claimed invention, as recited in amended independent claims 1, 28, 55, and 83, and in the claims that depend from them are patentable over the combination of Hanover et al. (US 5,196,002) and Duhaylongsod et al. (US 6,127,410), for the reasons cited hereinabove.

Claim Rejections – 35 USC § 103(a) – Hanover et al.

Claims 19, 46, 64 and 92 were rejected under 35 USC 103(a) as obvious over Hanover et al.

Respectfully, each of claims 19, 46, 64 and 92 is dependent on one of amended independent claims 1, 28, 55, and 83. Applicant maintains that the claimed invention, as recited in amended independent claims 1, 28, 55, and 83, and in the claims that depend on them are patentable over Hanover et al. (US 5,196,002), for the reasons cited hereinabove.

Conclusion

All matters raised by the Examiner have been addressed.

Claims 1 – 23, 25 – 50, and 52 – 110 are now pending in the application.

In view of the foregoing, it is believed this application is now in condition for allowance, and an early Notice of Allowance is respectfully solicited.

Respectfully submitted,

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